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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,200	03/26/2004	Wayne Livingston Cody	PC25562A	1789

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WARNER-LAMBERT COMPANY
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EXAMINER	
CHANG, CELIA C	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,200	CODY ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *07 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-19,27-32,34-37,41-48 and 51-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-19,27-32,34-37,41-48 and 51-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 57 when W is aryl, T is aryl and claims 1-56, 58 and 67 reading on claim 57, i.e. the 4-phenyl-3-arylalkylamino-piperidines in the reply filed on Dec. 7, 2004 is acknowledged.

Claims 20-26, 33, 38-40, 49 and 50 have been canceled. Claims 59-66 have been withdrawn. Currently amended claims 1-19, 27-32, 34-37, 41-48, 51-58 and 67 reading on the elected compounds when W is aryl, T is aryl i.e. the 4-phenyl-3-arylalkylamino-piperidines are prosecuted.

It is recommended that the non-elected scope wherein W and T are not aryl be deleted from the claims.

Claims 59-66 method of use claims will be rejoined with the prosecution of the compounds to the extend of the elected compound and examined. The restriction between the compounds and the process of use are withdrawn. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 is self conflicting since this is a pharmaceutical composition yet without a dosage limitation. Please note that pharmaceutical composition by definition can neither be ineffective nor toxic. It is recommended that the "therapeutically effective amount" be incorporated.

3. Claim 65 recites the limitation "providing end organ protection" in the method of using the claimed compounds. There is insufficient antecedent basis for this limitation in the claim.

Please note that there is no description or definition of the term "providing end organ protection" in the specification. It is not understood what constitutes end organ or protecting from what.

4. Claims 60-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Please note that the term "preventing.....to the mammal in need thereof" is self conflicting. Once a disorder or symptom has been diagnosed and the subject is in need of treatment, the de novo "prevention" can not be made. The "prevention" can only be in preventing recurrence of disorder or pathology, i.e. a maintenance dose preventing recurrence of disorder or symptom which is embraced by the term "treatment". It is recommended that the term "and preventing" be deleted from the claims.

5. Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Cecil textbook of medicine is hereby provided for applicant's convenience. Please note that the term "myocardial infarction" is defined being an *irreversible* cardiac injury i.e. necrosis of the cardiac cells. Since such condition is irreversible, treating such condition by rennin inhibitor can not be achieved. No description or enablement can be found in the specification that the claimed compound can reverse the cellular injury or necrosis of the heart muscle. Especially, the dosage of treating myocardial infarction must be an amount affecting the infarct condition for which no nexus of support or enabling description can be found in the specification.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-19, 27-32, 34-37, 41-48, 51-58 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binggeli et al. US 6,051,712 (cited on 1449) in view of Binggeli et al. CA 126 structure delineation.

Determination of the scope and content of the prior art (MPEP §2141.01)

Bingelli et al. US 6,051,712 generically disclosed the claimed compound, process of making, as renin inhibitors, see col. 1-3, col. 17-34 processes and col. 51-52.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Bingelli et al. '712 disclosed all the elements of the claims except a particular species wherein X is N was not exemplified. Structurally very similar species has been exemplified (see claims 1-4) and Binggeli et al. CA delineated other exemplified compounds enabling the X being various moieties under the disclosed genus at col. 2 last two lines-col. 3 line 16.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the generic teaching of the Bingelli et al. '712 reference with the multiple variation enabled and guided by the examples would be motivated to prepare all of the variations as taught by Bingelli et al. since the variation as generically taught were exemplified to have similar activity. The modification of the compounds as claimed in claims 1-4 of Bingelli et al. with and X is N variation would be the instant compounds of claims 43-48, 51-57. In absence of unexpected results, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Feb. 17, 2005

Celia Chang
Primary Examiner
Art Unit 1625